JAN 19 2007

Summary of Safety and Effectiveness

Submitter: Michael Kvitnitsky
ACCIN Corporation
1033 US Highway 46, Suite A204
Clifton, NJ 07103

Date Prepared: December 19, 2006

Device: ACCIN UNI-Knee System

Classification: 87 HSX - Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal Polymer, 21 CFR 888.3520, Class II

Predicate Device: Accin UNI-Knee System – K060670
Zimmer Unicompartmental Knee System – K033363

Device Description: The ACCIN UNI-Knee System consists of Cobalt Chrome femoral component and tibial tray and a polyethylene tibial insert.

Intended Use: The ACCIN UNI-Knee System components are for use in Unicompartmental knee arthroplasty as a result of:

- Moderately disabling joint disease of the knee resulting from painful osteoarthritis or post traumatic arthritis;
- Correction of functional deformities;
- Revision of previous unsuccessful unicompartmental knee replacement or other procedure;
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

These components are single use only and are intended for implantation with bone cement.

Comparison to Predicates:
The ACCIN UNI-Knee system consists of cobalt chrome femoral and tibial components and a polyethylene insert. The Accin UNI-Knee additional tibia bearing components are equivalent to the currently marketed Accin UNI-Knee tibia bearing components with the exception of thickness. The Accin UNI-Knee additional tibia bearing components will make the bearing thickness range (8mm to 14mm) equivalent to that of the currently marketed Zimmer Unicompartmental Knee System.

Description of Device Modification:
This submission is intended to address a line extension of the Accin UNI-Knee system. The line extension includes additional tibia bearing components 11mm, 12mm, 13mm and 14mm, making the tibia bearing thickness range 8mm to 14mm, in 1mm increments. No other changes or additions are being made.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2007

Accin Corporation
% Mr. Michael Kvitnitsky
President
1033 US Highway 46 East
Suite A204
Clifton, New Jersey 07103

Re: K063782
Trade/Device Name: ACCIN UNI-Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: December 19, 2006
Received: December 26, 2006

Dear Mr. Kvitnitsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known):_____

Device Name: ACCIN UNI-Knee System

Indications for Use:

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The ACCIN UNI-Knee System components are for use in Unicompartmental knee arthroplasty as a result of:

- Moderately disabling joint disease of the knee resulting from painful osteoarthritis or post traumatic arthritis;
- Correction of functional deformities;
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- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

These components are single use only and are intended for implantation with bone cement.

Prescription Use ___X____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063782